

CONSULTATIVE DOCUMENT

**PROPOSALS FOR THE CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH (AMENDMENT)
REGULATIONS 1992**

AND

**AMENDMENTS TO APPROVED CODES OF PRACTICE: CONTROL OF SUBSTANCES HAZARDOUS TO
HEALTH AND CONTROL OF CARCINOGENIC SUBSTANCES**

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INTRODUCTION

1 This document sets out the proposals of the Health and Safety Commission (HSC) for draft Regulations to amend the Control of Substances Hazardous to Health Regulations 1988 (COSHH) and amendments to the supporting Approved Codes of Practice: Control of Substances Hazardous to Health (General ACOP) and Control of Carcinogenic Substances (Carcinogens ACOP). The main amendments stem from the need to implement the Carcinogens Directive (90/394/EEC). There is also a proposal arising from the on-going programme of substance reviews by the Advisory Committee on Toxic Substances (ACTS). The HSC has been advised on this by ACTS, the membership of which includes representatives of the Confederation of British Industry, the Trades Union Congress and Local Authorities, together with other experts in the field of occupational health.

2 The views of interested parties are sought on the draft amending Regulations and the amendments to the Approved Codes of Practice. After consideration of all comments received the Commission intends to submit proposals to the Secretary of State with a view to the making of amending Regulations and the approval of the amendments to the Codes of Practice. The revised Schedule 1 to the Regulations will also be reproduced in HSE Guidance Booklet EH40/93.

3 There have been two previous sets of amending Regulations to COSHH, coming into effect on 1 January 1991 and 1 January 1992 respectively. Each set led to publication by HMSO of revised editions of the COSHH General ACOP and Carcinogens ACOP. The revised Schedule 1 in each case was incorporated in the annual revision of HSE Guidance Booklet EH40.

BACKGROUND

4 This Consultative Document is one of a series setting out proposals to implement Directives made under Article 118A of the Treaty of Rome and adopted by the Council of Ministers of the European Community for implementation by 1 January 1993. The Carcinogens Directive was approved on 28 June 1990.

5 In 1989 and 1990 the European Council of Ministers agreed, on the proposal of the European Commission, to a Framework Directive on Health and Safety, together with other directives dealing with specific aspects such as the workplace, the use of work equipment, the use of personal protective equipment, manual handling of loads, work with display screen equipment and work with carcinogens.

6 Each Directive is, or will be, the subject of its own Consultative Document containing proposals for implementation by regulations made under Section 15 of the Health and Safety at Work, etc Act 1974 (HSWA). The Consultative Documents are expected to be published between October 1991 and early 1992.

7 The Health and Safety Commission's policy on the negotiation of EC's programme of health and safety directives has been set out in its Plans of Work for 1990-1 and 1991-2. We recognise that good progress has been made with the modernisation of British Health and Safety law by means of regulations made under HSWA and that had stood us in good stead in advancing British models as a basis for EC provisions. Nevertheless we have had to recognise that the outcome of negotiations at Community level, especially under the new system of qualified voting introduced by the Single European Act would necessarily involve the UK - and other countries - in compromises which entail that changes and additions necessarily would have to be made to UK health and safety regulations to meet the objectives of the directives. This is particularly the case because the provisions of EC directives tend to be more prescriptive and detailed than objective setting regulations made under HSWA in the UK.

8 The strategy of the Health and Safety Commission in putting forward proposals for implementing the Framework and associated directives is:

(a) to avoid disrupting the basic framework established by HSWA, and also minimising change to the most recent regulations;

(b) to continue where appropriate the modernisation of health and safety law made prior to 1974 and to take the opportunity to repeal outdated legislation;

(c) to further the HSC/E philosophy of introducing control measures appropriate to the risk;

(d) to propose regulations which meet the directive, but which generally do not go beyond it, so as to minimise the impact of alterations in the law at a time when the requirements of the EC necessarily mean considerable changes in the law. Nevertheless the Commission proposes where appropriate to apply the directives to the self employed and to public safety in conformity with the approach adopted in the HSWA and subsequent regulations.

Precisely how this is to be done depends on the terms of each directive and its relationships to UK law.

Carcinogens Directive (90/394/EEC)

9 During the EC negotiations the UK was successful in aligning most aspects of the Directive with requirements of existing legislation such as COSHH. However, full implementation of the Directive will nevertheless require some adjustments to COSHH. In particular, in the light of recent experience with other Directives, it has been decided that certain prescriptive aspects of the Directive at present covered by guidance in the Carcinogens ACOP should be implemented by moving that guidance into a new Schedule to the Regulations.

10 In addition, new regulations to meet the requirements of the Workplace Directive (89/654/EEC) and the Safety Framework Directive (89/391/EEC) will implement parts of the Carcinogens Directive not covered by COSHH; the Department of Transport will implement the provisions of the Directive in relation to sea travel, which is excluded from COSHH; and the Health and Safety Commission intends to consider during the course of 1992 how the Directive should be implemented in relation to those provisions of the COSHH Regulations which do not apply to underground work in mines.

11 The Preparations Directive (88/379/EEC) has classified all forms of fibrous asbestos as category 1 carcinogens. They will consequently have to be labelled with the risk phrase R45: "May cause cancer". However proposals for dealing with asbestos are not included in this consultative document since

the Preparations Directive has not yet been implemented in the UK. A further consultation document will be published on implementing the Carcinogens Directive for work with asbestos.

Definition of Carcinogens

12 At present, carcinogens are defined for the purposes of COSHH in Appendix 1 to the Carcinogens ACOP. This details substances and processes to which the Code applies, namely any substance which has been assigned the risk phrase R45: "May cause cancer" under the Classification, Packaging and Labelling of Dangerous Substances Regulations 1984 and which is listed in Part 1A1 of the latest edition of the list approved under those regulations; and also any of the further substances or processes listed in paragraph 2 of Appendix 1 to the ACOP.

13 When the Preparations Directive (88/379/EEC) is implemented, a new definition will be possible based on the classification system used in that Directive. Until then, it is proposed to incorporate a revised definition based on the existing legislation.

The General and Carcinogens ACOPs

14 The General and Carcinogens ACOPs give practical guidance to support the COSHH Regulations and will consequently need amendment to reflect the changes implementing the Carcinogens Directive. The proposed text of the General ACOP is at appendix D and that of the Carcinogens ACOP at Appendix E.

COSHH Schedule 1 - substances with maximum exposure limits (MELs)

15 Under regulation 7 of COSHH, an employer's duty is to prevent, or, where this is not reasonably practicable, adequately control exposure to hazardous substances. For certain substances hazardous by inhalation, the regulation gives direction about the meaning of adequate control. These are substances for which a MEL has been specified in Schedule 1 to the Regulations or for which the HSC has approved an occupational exposure standard (OES).

16 Where there is exposure to a substance for which a MEL is specified in Schedule 1, regulation 7 directs that the control of exposure shall, so far

as the inhalation of that substance is concerned, only be treated as being adequate if the level of exposure is reduced so far as is reasonably practicable and in any case below the maximum exposure limit.

17 Appendix F to this document gives details of a proposal, arising from the on-going review of substances by ACTS, that a MEL should be set for Bis(chloromethyl) ether (BCME), a known lung carcinogen. It is also proposed to make a slight adjustment to the derived equivalent value in mg m^{-3} of the MEL for benzene as a result of using a more accurate conversion process.

Other changes to COSHH arising from implementation of EC Directives

18 Two other HSE Consultative Documents also propose changes to the COSHH Regulations in connection with the implementation of Directives. They are mentioned here for information; full details and addresses for comments are given in the Consultative Documents themselves:

- (a) "Personal Protective Equipment at Work Regulations" (reference CD 38/91). To implement EC Directive 89/656/EEC on the use of personal protective equipment, the following amendments are proposed:
 - (i) Regulation 7: to recognise the testing and certification requirements of EC Personal Protective Equipment Product Directive 89/686/EEC. This will also involve consequential amendments to the COSHH General ACOP; and
 - (ii) Regulations 8 and 9: changes concerned with returning personal protective equipment to accommodation provided and keeping it in a clean condition.
- (b) "The Workplace (Health, Safety and Welfare) Regulations 199-". The proposed Regulations are to implement the Workplace Directive (89/654/EEC) and include requirements for the provision of facilities for washing, clothing accommodation, eating and drinking which overlap with existing guidance in the COSHH General ACOP. It is proposed that cross-references to the new Regulations should be included in the ACOP.

OUTLINE OF PROPOSALS

COSHH Regulations - Implementation of Carcinogens Directive

Regulation 2

19 The word 'carcinogen' is defined for the purposes of the Regulations in an addition to Regulation 2(1) (see page 21). The definition is generally similar to that already used in Appendix 1 of the Carcinogens ACOP but includes preparations as well as substances, and adds the risk phrase R49: "May cause cancer by inhalation" to the existing scope. A new, more comprehensive definition will become possible when the Preparations Directive (88/379/EEC) has been implemented.

Regulation 6(2) and the General ACOP

20 The Carcinogens Directive requires assessment of risk from carcinogens to be reviewed regularly. COSHH has therefore to be amended in relation to carcinogens, since at present an assessment only has to be reviewed when there are changes in circumstances which affect its validity. A similar requirement for regular review will also have to be incorporated into COSHH for substances covered by the Biological Agents Directive (90/679/EEC) when that Directive is implemented next year. It is therefore proposed to take the present opportunity to include in COSHH a general requirement for regular review of assessments in relation to all hazardous substances, whether they are known carcinogens or not. In any case it would be difficult, if not impracticable, to separate assessments for carcinogens, which would require regular review, from those for other substances which did not.

21 New accompanying text is proposed (at Appendix D) for the General ACOP giving practical guidance on this requirement, telling employers that in order to ensure that regular reviews are done, their assessment should include a decision on the maximum period which should elapse between reviews, even where there have been no obvious changes in circumstances. This would encourage forward planning. For example, existing controls for a process might be adequate, but a periodic review might find that new control measures had become available since the last review which were easier to maintain or more cost-effective.

Regulation 7 and Schedule 10

22 The main changes to the Regulations are effected by the provision of a new Schedule 10. Part I of the Schedule lists other substances and processes to which the definition of 'carcinogen' applies. This identical list currently appears in paragraph 2 of Appendix 1 to the Carcinogens ACOP. Part II describes the application of Regulation 7 to carcinogens. It lists the measures which must be taken to prevent or control exposure to carcinogens additional to those measures required for hazardous substances in general. These measures are not new; they are all equivalent to similar requirements of the present Carcinogens ACOP. Appendix C to this document compares the resulting provisions of Regulation 7 for non-carcinogens and carcinogens.

Regulations 10(3)(a) and 11(3)

23 The Carcinogens Directive requires that monitoring and health surveillance records for named individuals working with carcinogens must be kept for 40 years. Under COSHH at present such records need only be kept for 30 years. To avoid the impracticability of requiring records to be kept for differing periods, it is proposed that the new 40 year period be adopted for all personal monitoring and health surveillance records which have to be kept, whether the hazardous substances involved are carcinogenic or not.

COSHH General ACOP

24 Appendix D shows proposed changes to the General ACOP arising from the implementation of the Carcinogens Directive:

Substances hazardous to health

25 A new paragraph 2 explains where the special provisions and guidance relating to carcinogens are to be found within the publication. Bearing in mind the special nature of risks from carcinogens and other substances with potentially irreversible health effects, paragraph 2 emphasises the particular importance of a precautionary policy towards risks from such substances.

Regular review of assessments

26 A new paragraph 26 outlines the arrangements which should be made to ensure that assessments are reviewed regularly. Paragraph 27 gives examples of the purpose and nature of reviews triggered by those arrangements.

Prevention or control of exposure to hazardous substances

27 This section (paragraphs 28-45 of the draft) is slightly rearranged to give more emphasis to the hierarchy of controls - the importance of prevention or substitution and the need to avoid reliance on personal protective equipment. A new paragraph 32 introduces the special provisions in the Regulations relating to carcinogens.

Carcinogens ACOP

28 A number of changes are necessary to the wording of the Carcinogens ACOP in order to implement the details of the Carcinogens Directive. A revised draft showing the proposed changes is at Appendix E.

29 The existing Appendix 1, listing substances and processes to which the Code applies, becomes redundant, its contents being embodied in the COSHH Regulations themselves, in Regulation 2(1) and Schedule 10 Part I.

Changes to COSHH Schedule 1 (See Appendix F)

Proposed MEL for Bis(Chloromethyl) Ether (BCME)

30 A MEL is proposed for bis(chloromethyl) ether (BCME) at a concentration of 0.001 ppm 8-hour TWA. This recognises that BCME is an extremely potent lung carcinogen and that it is not at present possible to identify a threshold for its carcinogenicity.

Derived equivalent value of the MEL for Benzene

31 It is proposed to make a slight adjustment to the derived equivalent value in mg m^{-3} of the MEL for benzene as a result of using a more accurate

conversion process. This does not involve any change to the MEL itself which is set at 5 ppm calculated as an 8-hour time-weighted average (TWA).

IMPLICATIONS FOR INDUSTRY

Implementation of the Carcinogens Directive

32 The changes necessary to the legislation in implementing the Directive consist almost entirely of incorporation of material from the General or Carcinogens ACOPs into the Regulations themselves. Therefore, since industry should already have been complying with the guidance in those ACOPs, there should be no significant implications for employers in complying with the amended Regulations. Although the provision of equally effective alternatives to ACOP requirements allowed under Section 17(2) of the Health and Safety at Work etc. Act 1974 does not apply to regulations, there are no known instances of alternatives which would be rendered illegal by this change of status.

33 Regular assessment should not have any serious implications for industry. Many firms already have systems in place for ensuring that assessments are kept up to date, and the modest cost to others obliged to do so under the proposed arrangements may be outweighed by benefits from improved planning and better standards of control.

34 The proposed requirement that monitoring and health surveillance records for named individuals should be kept for 40 rather than 30 years will have no significant impact on most of industry.

Maximum exposure limit for BCME

35 Occupational exposures to BCME through its deliberate generation or presence as an impurity or by-product are known to occur at four sites in the UK. Although additional investment may be necessary in some cases, this will not be disproportionate given the particularly potent nature of this carcinogen.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 28 June 1990

on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

(90/394/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 118a thereof,

Having regard to the proposal from the Commission ⁽¹⁾, drawn up following consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work,

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Article 118a of the Treaty provides that the Council is to adopt, by means of Directives, minimum requirements in order to encourage improvements, especially in the working environment, so as to guarantee better protection of the health and safety of workers;

Whereas, according to that Article, such directives must avoid imposing administrative, financial and legal constraint in a way which would hold back the creation and development of small and medium-sized undertakings;

Whereas the Council resolution of 27 February 1984 on a second action programme of the European Communities on safety and health at work ⁽⁴⁾ provides for the development of protective measures for workers exposed to carcinogens;

Whereas the Commission communication on its programme concerning safety, hygiene and health at work ⁽⁵⁾ provides for the adoption of Directives to guarantee the health and safety of workers;

Whereas compliance with the minimum requirements designed to guarantee a better standard of health and safety as regards the protection of workers from the risks related to exposure to carcinogens at work is essential to ensure the health and safety of workers;

Whereas this Directive is an individual Directive within the meaning of Article 16 (1) of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the health and safety of workers at work ⁽⁶⁾; whereas therefore the provisions of that Directive are fully applicable to the exposure of workers to carcinogens, without prejudice to more stringent and/or specific provisions contained in this Directive;

Whereas Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽⁷⁾, as last amended by Directive 88/490/EEC ⁽⁸⁾, contains a list of dangerous substances, together with particulars on the classification and labelling procedures in respect of each substance;

Whereas Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and

⁽¹⁾ OJ No C 34, 8. 2. 1988, p. 9.

⁽²⁾ OJ No C 158, 26. 6. 1989, p. 121 and OJ No C 149, 18. 6. 1990.

⁽³⁾ OJ No C 208, 8. 8. 1988, p. 43.

⁽⁴⁾ OJ No C 67, 8. 3. 1984, p. 2.

⁽⁵⁾ OJ No C 28, 3. 2. 1988, p. 1.

⁽⁶⁾ OJ No L 183, 29. 6. 1989, p. 1.

⁽⁷⁾ OJ No 196, 16. 8. 1967, p. 1.

⁽⁸⁾ OJ No L 259, 19. 9. 1988, p. 1.



administrative provisions relating to the classification, packaging and labelling of dangerous preparations ⁽¹⁾, as last amended by Directive 89/178/EEC ⁽²⁾, contains particulars on the classification and labelling procedures in respect of such preparations;

Whereas the plan of action 1987 to 1989 adopted under the 'Europe against cancer' programme provides for support for European studies on the possible cancer risks of certain chemical substances;

Whereas, although current scientific knowledge is not such that a level can be established below which risks to health cease to exist, a reduction in exposure to carcinogens will nonetheless reduce those risks;

Whereas nevertheless, in order to contribute to a reduction in these risks, limit values and other directly related provisions should be established for all those carcinogens for which the available information, including scientific and technical data, make this possible;

Whereas preventive measures must be taken for the protection of the health and safety of workers exposed to carcinogens;

Whereas this Directive lays down particular requirements specific to exposure to carcinogens;

Whereas this Directive constitutes a practical aspect of the realization of the social dimension of the internal market;

Whereas, pursuant to Decision 74/325/EEC ⁽³⁾, as last amended by the 1985 Act of Accession, the Advisory Committee on Safety, Hygiene and Health Protection at Work is to be consulted by the Commission with a view to drawing up proposals in this field,

HAS ADOPTED THIS DIRECTIVE:

SECTION I

GENERAL PROVISIONS

Article 1

Objective

1. This Directive, which is the sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC, has as its aim the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens at work.

It lays down particular minimum requirements in this area, including limit values.

2. This Directive shall not apply to workers exposed only to radiation covered by the Treaty establishing the European Atomic Energy Community.

3. Directive 89/391/EEC shall apply fully to the whole area referred to in paragraph 1, without prejudice to more stringent and/or specific provisions contained in this Directive.

Article 2

Definition

For the purposes of this Directive, 'carcinogen' means:

- (a) a substance to which, in Annex I to Directive 67/548/EEC, the risk-phrase R 45 'may cause cancer' is applied;
- (b) a preparation which, under Article 3 (5) (i) of Directive 88/379/EEC, must be labelled as R 45 'may cause cancer';
- (c) a substance, a preparation or a process referred to in Annex I as well as a substance or preparation released by a process referred to in Annex I.

Article 3

Scope — determination and assessment of risks

1. This Directive shall apply to activities in which workers are or are likely to be exposed to carcinogens as a result of their work.
2. In the case of any activity likely to involve a risk of exposure to carcinogens, the nature, degree and duration of workers' exposure must be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken.

The assessment must be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens.

The employer must supply the authorities responsible at their request with the information used for making the assessment.

3. Furthermore, when assessing the risk, account shall be taken of all other cases of major exposure, such as those with harmful effects on the skin.

4. When the assessment referred to in paragraph 2 is carried out, employers shall give particular attention to any effects concerning the health or safety of workers at

⁽¹⁾ OJ No L 187, 16. 7. 1988, p. 14.

⁽²⁾ OJ No L 64, 8. 3. 1989, p. 18.

⁽³⁾ OJ No L 185, 9. 7. 1974, p. 15.

particular risk and shall, *inter alia*, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens.

SECTION II

EMPLOYERS' OBLIGATIONS

Article 4

Reduction and replacement

1. The employer shall reduce the use of a carcinogen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be.

2. The employer shall, upon request, submit the findings of his investigations to the relevant authorities.

Article 5

Prevention and reduction of exposure

1. Where the results of the assessment referred to in Article 3 (2) reveal a risk to workers' health or safety, workers' exposure must be prevented.

2. Where it is not technically possible to replace the carcinogen by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen is, in so far as is technically possible, manufactured and used in a closed system.

3. Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible.

4. Wherever a carcinogen is used, the employer shall apply all the following measures:

- (a) limitation of the quantities of a carcinogen at the place of work;
- (b) keeping as low as possible the number of workers exposed or likely to be exposed;
- (c) design of work processes and engineering control measures so as to avoid or minimize the release of carcinogens into the place of work;

- (d) evacuation of carcinogens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;
- (e) use of existing appropriate procedures for the measurement of carcinogens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;
- (f) application of suitable working procedures and methods;
- (g) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
- (h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;
- (i) information for workers;
- (j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens;
- (k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;
- (l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;
- (m) means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers.

Article 6

Information for the competent authority

Where the results of the assessment referred to in Article 3 (2) reveal a risk to workers' health or safety, employers shall, when requested, make available to the competent authority appropriate information on:

- (a) the activities and/or industrial processes carried out, including the reasons for which carcinogens are used;
- (b) the quantities of substances or preparations manufactured or used which contain carcinogens;
- (c) the number of workers exposed;
- (d) the preventive measures taken;
- (e) the type of protective equipment used;
- (f) the nature and degree of exposure;
- (g) the cases of replacement.

*Article 7***Unforeseen exposure**

1. In the event of an unforeseeable event or an accident which is likely to result in an abnormal exposure of workers, the employer shall inform the workers thereof.

2. Until the situation has been restored to normal and the causes of the abnormal exposure have been eliminated:

- (a) only those workers who are essential to the carrying out of repairs and other necessary work shall be permitted to work in the affected area;
- (b) the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear; the exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker;
- (c) unprotected workers shall not be allowed to work in the affected area.

*Article 8***Foreseeable exposure**

1. For certain activities such as maintenance, in respect of which it is foreseeable that there is the potential for a significant increase in exposure of workers, and in respect of which all scope for further technical preventive measures for limiting workers' exposure has already been exhausted, the employer shall determine, after consultation of the workers and/or their representatives in the undertaking or establishment, without prejudice to the employer's responsibility, the measures necessary to reduce the duration of workers' exposure to the minimum possible and to ensure protection of workers while they are engaged in such activities.

Pursuant to the first subparagraph, the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear as long as the abnormal exposure persists; that exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker.

2. Appropriate measures shall be taken to ensure that the areas in which the activities referred to in the first subparagraph of paragraph 1 take place are clearly demarcated and indicated or that unauthorized persons are prevented by other means from having access to such areas.

*Article 9***Access to risk areas**

Appropriate measures shall be taken by employers to ensure that access to areas in which the activities in respect of which the results of the assessment referred to in Article 3 (2) reveal

a risk to workers' safety or health take place are accessible solely to workers who, by reason of their work or duties, are required to enter them.

*Article 10***Hygiene and individual protection**

1. Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens, to take appropriate measures to ensure that:

- (a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens;
- (b) workers are provided with appropriate protective clothing or other appropriate special clothing; separate storage places are provided for working or protective clothing and for street clothes;
- (c) workers are provided with appropriate and adequate washing and toilet facilities;
- (d) protective equipment is properly stored in a well-defined place;
it is checked and cleaned if possible before, and in any case after, each use;
defective equipment is repaired or replaced before further use.

2. Workers may not be charged for the cost of these measures.

*Article 11***Information and training of workers**

1. Appropriate measures shall be taken by the employer to ensure that workers and/or workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions, concerning:

- (a) potential risks to health, including the additional risks due to tobacco consumption;
- (b) precautions to be taken to prevent exposure;
- (c) hygiene requirements;
- (d) wearing and use of protective equipment and clothing;
- (e) steps to be taken by workers, including rescue workers, in the case of incidents and to prevent incidents.

The training shall be:

- adapted to take account of new or changed risk, and
- repeated periodically if necessary.

2. Employers shall inform workers of installations and related containers containing carcinogens, ensure that all containers, packages and installations containing carcinogens are labelled clearly and legibly, and display clearly visible warning and hazard signs.

Article 12

Information for workers

Appropriate measures shall be taken to ensure that:

- (a) workers and/or any workers' representatives in the undertaking or establishment can check that this Directive is applied or can be involved in its application, in particular with regard to:
 - (i) the consequences for workers' safety and health of the selection, wearing and use of protective clothing and equipment, without prejudice to the employer's responsibility for determining the effectiveness of protective clothing and equipment;
 - (ii) the measures determined by the employer which are referred to in the first subparagraph of Article 8 (1), without prejudice to the employer's responsibility for determining such measures;
- (b) workers and/or any workers' representatives in the undertaking or establishment are informed as quickly as possible of abnormal exposures, including those referred to in Article 8, of the causes thereof and of the measures taken or to be taken to rectify the situation;
- (c) the employer keeps an up-to-date list of the workers engaged in the activities in respect of which the results of the assessment referred to in Article 3 (2) reveal a risk to workers' health or safety, indicating, if the information is available, the exposure to which they have been subjected;
- (d) the doctor and/or the competent authority as well as all other persons who have responsibility for health and safety at work have access to the list referred to in subparagraph (c);
- (e) each worker has access to the information on the list which relates to him personally;
- (f) workers and/or any workers' representatives in the undertaking or establishment have access to anonymous collective information.

Article 13

Consultation and participation of workers

Consultation and participation of workers and/or their representatives in connection with matters covered by this Directive, including the Annexes hereto, shall take place in accordance with Article 11 of Directive 89/391/EEC.

SECTION III

MISCELLANEOUS PROVISIONS

Article 14

Health surveillance

1. The Member States shall establish, in accordance with national laws and/or practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in Article 3 (2) reveal a risk to health or safety.
2. The arrangements referred to in paragraph 1 shall be such that each worker shall be able to undergo, if appropriate, relevant health surveillance:
 - prior to exposure,
 - at regular intervals thereafter.

Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

3. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

In that event, a reassessment of the risk of exposure shall be carried out in accordance with Article 3 (2).

4. In cases where health surveillance is carried out, an individual medical record shall be kept and the doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual workers.

5. Information and advice must be given to workers regarding any health surveillance which they may undergo following the end of exposure.

6. In accordance with national laws and/or practice:

- workers shall have access to the results of the health surveillance which concern them, and
- the workers concerned or the employer may request a review of the results of the health surveillance.

7. Practical recommendations for the health surveillance of workers are given in Annex II.

8. All cases of cancer identified in accordance with national laws and/or practice as resulting from occupational exposure to a carcinogen shall be notified to the competent authority.

Article 15

Record-keeping

1. The list referred to in Article 12 (c) and the medical record referred to in Article 14 (4) shall be kept for at least 40 years following the end of exposure, in accordance with national laws and/or practice.

2. Those documents shall be made available to the responsible authority in cases where the undertaking ceases activity, in accordance with national laws and/or practice.

Article 16

Limit values

1. The Council shall, in accordance with the procedure laid down in Article 118a of the Treaty, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens for which this is possible, and, where necessary, other directly related provisions.

2. Limit values and other directly related provisions shall be set out in Annex III.

Article 17

Annexes

1. Annexes I and III may be amended in accordance only with the procedure laid down in Article 118a of the Treaty.

2. Purely technical adjustments to Annex II in the light of technical progress, changes in international regulations or

specifications and new findings in the field of carcinogens shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.

Article 18

Use of data

The Commission shall have access to the use made by the competent national authorities of the information referred to in Article 14 (8).

Article 19

Final provisions

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1992.

Should Directives 67/548/EEC or 88/379/EEC be amended by amending Directives after notification of this Directive with respect to the substances and preparations referred to in Article 2 (a) and (b), Member States shall bring into force the laws, regulations and administrative provisions necessary to introduce the amendments in question into the provisions referred to in the first subparagraph by the deadlines laid down for implementation of such amending Directives.

Member States shall forthwith inform the Commission that the provisions referred to in this paragraph have been brought into force.

2. Member States shall communicate to the Commission the provisions of national law already adopted or which they adopt in the future in the field governed by this Directive.

Article 20

This Directive is addressed to the Member States.

Done at Luxembourg, 28 June 1990.

For the Council

The President

M. GEOGHEGAN-QUINN

ANNEX I

List of substances, preparations and processes

(Article 2 (c))

1. Manufacture of auramine.
 2. Work involving exposure to aromatic polycyclic hydrocarbons present in coal soots, tar, pitch, fumes or dust.
 3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes.
 4. Strong acid process in the manufacture of isopropyl alcohol.
-

ANNEX II

Practical recommendations for the health surveillance of workers

(Article 14 (7))

1. The doctor and/or authority responsible for the health monitoring of workers exposed to carcinogens must be familiar with the exposure conditions or circumstances of each worker.
2. Health monitoring of workers must be carried out in accordance with the principles and practices of occupational medicine; it must include at least the following measures:
 - keeping records of a worker's medical and occupational history,
 - a personal interview,
 - where appropriate, biological monitoring, as well as detection of early and reversible effects.

Further tests may be decided upon for each worker when he is the subject of health monitoring, in the light of the most recent knowledge available to occupational medicine.

ANNEX III

Limit values and other directly related provisions

(Article 16)

- A. Limit values
p.m.
 - B. Other directly related provisions
p.m.
-

DRAFT CONTROL OF SUBSTANCES
HAZARDOUS TO HEALTH (AMENDMENT)
REGULATIONS 1992

HEALTH AND SAFETY

The Control of Substances Hazardous to Health (Amendment) Regulations 1992

Draft proposals for regulations to be made under section 15(1) and (2) of, and paragraphs 1(1)b, (2) and (3), 7, 10, 11, 13(1), 15(1), 16 and 20 of Schedule 3 to, the Health and Safety at Work etc. Act 1974.

Citation, commencement and interpretation

1. - (1) These Regulations may be cited as the Control of Substances Hazardous to Health (Amendment) Regulations 1992 and shall come into force on 1st January 1993.

(2) In these Regulations, "the principal Regulations" means The Control of Substances Hazardous to Health Regulations 1988 **(a)**.

Amendment to the principal Regulations

2. - (1) The regulations in the principal Regulations shall be amended in accordance with Schedule 1 to these Regulations.

(2) For Schedule 1 to the principal Regulations there shall be substituted the Schedule set out in Schedule 2 to these Regulations.

(a) S.I. 1988/1657, amended by S.I. 1991/2431.

(3) There shall be inserted as Schedule 10 to the principal Regulations the Schedule set out in Schedule 3 to these Regulations.

Revocations

3. Regulation 2(2) of, and Schedule 1 to, the Control of Substances Hazardous to Health (Amendment) Regulations 1991 **(a)** shall be revoked.

(a) S.I. 1991/2431.

SCHEDULE 1

AMENDMENTS TO THE PRINCIPAL REGULATIONS

1. In regulation 2(1) of the principal Regulations, after the definition of "approved list" insert the following definition -

"carcinogen" means -

- (a) any substance or preparation which when classified in accordance with the classification provided for by regulation 5 of the Classification, Packaging and Labelling of Dangerous Substances Regulations 1984 (S.I. 1984/1244, amended by S.I. 1986/1922, S.I. 1988/766, S.I. 1989/2208 and S.I. 1990/1255) is required to be labelled with the risk phrase R45 (may cause cancer) or R49 (may cause cancer by inhalation), whether or not the substance or preparation is required to be classified in accordance with those Regulations; or
- (b) any substance or preparation listed in Part I of Schedule 10 and any substance or preparation involved in a process specified in that Part which is a substance hazardous to health;'.

2. In regulation 6(2) of the principal Regulations, in the opening subparagraph after the words "shall be reviewed" insert the words "regularly and",

3. After paragraph (1) of regulation 7 of the principal Regulations insert the following paragraph -

"(1A) In its application to carcinogens, the following paragraphs of this regulation shall have effect subject to the provisions of Part II of Schedule 10."

4. In regulations 10(3)(a) and 11(3) of the principal Regulations for the words "30 years" substitute the words "40 years" in both places where those words appear.

SCHEDULE 2

SCHEDULE TO BE SUBSTITUTED AS SCHEDULE 1
TO THE PRINCIPAL REGULATIONS

Regulations 2(1), 7(4) and 12(2)

SCHEDULE 1

LIST OF SUBSTANCES ASSIGNED MAXIMUM EXPOSURE LIMITS

The maximum exposure limits of the dusts included in the list below refer to the total inhalable dust fraction, unless otherwise stated.

Substance	Formula	Reference periods			
		Long-term maximum exposure limit (8-hour TWA reference period)		Short-term maximum exposure limit (10-minute reference period)	
		ppm	mg m ⁻³	ppm	mg m ⁻³
Acrylamide	CH ₂ =CHCONH ₂	-	0.3	-	-
Acrylonitrile	CH ₂ =CHCN	2	4	-	-
Arsenic & compounds except arsine (as As)	As	-	0.1	-	-
Benzene	C ₆ H ₆	5	16	-	-
Bis(chloromethyl) ether	ClCH ₂ OCH ₂ Cl	0.001	0.005	-	-
Buta-1,3-diene	CH ₂ =CHCH=CH ₂	10	22	-	-
2-Butoxyethanol	C ₄ H ₉ OCH ₂ CH ₂ OH	25	120	-	-
Cadmium & cadmium compounds, except cadmium oxide fume and cadmium sulphide pigments (as Cd)	Cd	-	0.05	-	-
Cadmium oxide fume (as Cd)	CdO	-	0.05	-	0.05
Cadmium sulphide pigments (respirable dust as Cd)	CdS	-	0.04	-	-
Carbon disulphide	CS ₂	10	30	-	-

Chromium (VI) compounds (as Cr)	Cr	-	0.05	-	-
1,2-Dibromoethane (Ethylene dibromide)	BrCH ₂ CH ₂ Br	0.5	4	-	-
Dichloromethane	CH ₂ Cl ₂	100	350	-	-
2,2'-Dichloro-4,4'- methylene dianiline (MbOCA)	CH ₂ (C ₆ H ₃ ClNH ₂) ₂	-	0.005	-	-
2-Ethoxyethanol	C ₂ H ₅ OCH ₂ CH ₂ OH	10	37	-	-
2-Ethoxyethyl acetate	C ₂ H ₅ OCH ₂ CH ₂ OOCCH ₃	10	54	-	-
Ethylene oxide	CH ₂ CH ₂ O	5	10	-	-
Formaldehyde	HCHO	2	2.5	2	2.5
Grain dust		-	10	-	-
Hydrogen cyanide	HCN	-	-	10	10
Isocyanates, all (as-NCO)		-	0.02	-	0.07
*Man-made mineral fibre		-	5	-	-
2-Methoxyethanol	CH ₃ OCH ₂ CH ₂ OH	5	16	-	-
2-Methoxyethyl acetate	CH ₃ COOCH ₂ CH ₂ OCH ₃	5	24	-	-
Nickel and its inorganic compounds (except nickel carbonyl):	Ni				
water-soluble nickel compounds (as Ni)		-	0.1	-	-
nickel and water-insoluble nickel compounds (as Ni)		-	0.5	-	-
Rubber process dust		-	8	-	-
-Rubber fume		-	0.6	-	-
Silica, respirable crystalline	SiO ₂	-	0.4	-	-
Styrene	C ₆ H ₅ CH=CH ₂	100	420	250	1050
1,1,1-Trichloroethane	CH ₃ CCl ₃	350	1900	450	2450
Trichloroethylene	CCl ₂ =CHCl	100	535	150	802
*Vinyl chloride	CH ₂ =CHCl	7	-	-	-
Vinylidene chloride	CH ₂ =CCl ₂	10	40	-	-
Wood dust (hard wood)		-	5	-	-

*In addition to the maximum exposure limit specified above man-made mineral fibre is also subject to a maximum exposure limit of 2 fibres ml⁻¹, 8-hour TWA, when measured or calculated by a method approved by the Health and Safety Commission.

-Limit relates to cyclohexane soluble material.

#In addition to the maximum exposure limit specified above vinyl chloride is also subject to an overriding annual exposure limit of 3 ppm.

SCHEDULE 3

SCHEDULE TO BE INSERTED AS SCHEDULE 10
TO THE PRINCIPAL REGULATIONS

Regulations 2(1) and 7(1A)

SCHEDULE 10

SPECIAL PROVISIONS RELATING TO CARCINOGENS

PART I

OTHER SUBSTANCES AND PROCESSES TO WHICH
THE DEFINITION OF "CARCINOGEN" RELATES

Aflatoxins

Arsenic and inorganic arsenic compounds

Beryllium and beryllium compounds

Bichromate manufacture involving the roasting of chromite ore

Electrolytic chromium processes, excluding passivation, which involve
hexavalent chromium compounds

Mustard gas (B,B'Dichlorodiethyl sulphide)

Calcining, sintering or smelting of nickel copper matte or acid leaching or
electrorefining of roasted matte

Ortho-toluidine

Coal soots, coal tar, pitch and coal tar fumes

The following mineral oils:

- (i) unrefined and mildly refined vacuum distillates;
- (ii) catalytically cracked petroleum oils with final boiling points above 320°C;
- (iii) used engine oils;

Auramine manufacture

Leather dust in boot and shoe manufacture, arising during preparation and finishing

Hard wood dusts

Isopropyl alcohol manufacture (strong acid process)

Rubber manufacturing and processing giving rise to rubber process dust and rubber fume

Magenta manufacture

4-Nitrobiphenyl

PART II

APPLICATION OF REGULATION 7 TO CARCINOGENS

1. Nothing in this Part of the Schedule shall be taken as prejudicing the requirements of Regulation 7 as they relate to substances hazardous to health other than carcinogens.

2. In its application to carcinogens, for paragraph (2) of the principal Regulations substitute the following paragraph -

(2) Without prejudice to the generality of paragraph (1), where the assessment made under regulation 6 shows that it is not reasonably practicable to prevent exposure to a carcinogen by using an alternative substance or process, adequate control of exposure to the carcinogen shall be achieved by the application of all the following measures -

- (a) the total enclosure of the process and handling systems unless this is not reasonably practicable;
- (b) plant, processes and systems of work which minimise the generation of, or suppress and contain, spills, leaks, dust, fumes and vapours of carcinogens;
- (c) limitation of the quantities of a carcinogen at the place of work;
- (d) keeping the number of persons who might be exposed to a carcinogen to a minimum;
- (e) prohibiting eating, drinking and smoking in areas that may be contaminated by carcinogens;

- (f) the provision of hygiene measures including adequate washing facilities and regular cleaning of walls and surfaces;
- (g) the designation of those areas and installations which may be contaminated by carcinogens and the use of suitable warning signs;
- (h) the safe storage, handling and disposal of carcinogens and use of closed and clearly labelled containers.

3. In its application to carcinogens at the end of regulation 7 insert the following paragraph -

- (8) In the event of the failure of a control measure which might result in the escape of carcinogens into the workplace, the employer shall ensure that -
 - (a) only those persons who are responsible for the carrying out of repairs and other necessary work are permitted in the affected area and they are provided with appropriate respiratory protective equipment and protective clothing; and
 - (b) employees and other persons who may be affected are informed of the failure forthwith.

PROPOSED COSHH AMENDMENT REGULATIONS 1992 - REGULATION 7
COMPARISON OF PROVISIONS FOR CARCINOGENS AND OTHER
SUBSTANCES

HAZARDOUS SUBSTANCES OTHER THAN CARCINOGENS

(1) Every employer shall ensure that the exposure of his employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled.

[NB: The existing sub-para (2) below would remain in effect for hazardous substances other than carcinogens:]

(2) So far as is reasonably practicable, the prevention or adequate control of exposure of employees to a substance hazardous to health shall be secured by measures other than the provision of personal protective equipment.

(3) Where the measures taken in accordance with paragraph (2) do not prevent, or provide adequate control of, exposure to substances hazardous to the health of employees, then, in addition to taking those measures, the employer shall provide those employees with such suitable personal protective equipment as will adequately control their exposure to substances hazardous to health.

CARCINOGENS

(as for other substances)

(1A) In its application to carcinogens, the following paragraphs of this regulation shall have effect subject to the provisions of Part II of Schedule 10.

[NB: For carcinogens, the Schedule substitutes a different sub-para (2) and adds a new sub-para (8):]

(2) Without prejudice to the generality of paragraph (1), where the assessment made under regulation 6 shows that it is not reasonably practicable to prevent exposure to a carcinogen by using an alternative substance or process, adequate control of exposure to the carcinogen shall be achieved by the application of all the following measures -

- (a) the total enclosure of the process and handling systems unless this is not reasonably practicable;
- (b) plant, processes or systems of work which minimise the generation of, or suppress and contain, spills, leaks, dust, fumes and vapours of carcinogens;
- (c) limitation of the quantities of a carcinogen at the place of work;
- (d) keeping the number of persons who might be exposed to a carcinogen to a minimum;
- (e) prohibiting eating, drinking and smoking in areas that may be contaminated by carcinogens;
- (f) the provision of hygiene measures including adequate washing facilities and regular cleaning of walls and surfaces;
- (g) the designation of those areas and installations which may be contaminated by carcinogens and the use of suitable warning signs;
- (h) the safe storage, handling and disposal of carcinogens and use of closed and clearly labelled containers.

(as for other substances)

(4) Where there is exposure to a substance for which a maximum exposure limit is specified in Schedule 1, the control of exposure shall, so far as the inhalation of that substance is concerned, only be treated as being adequate if the level of exposure is reduced so far as is reasonably practicable and in any case below the maximum exposure limit.

(as for other substances)

(5) Without prejudice to the generality of paragraph (1), where there is exposure to a substance for which an occupational exposure standard has been approved, the control of exposure shall, so far as the inhalation of that substance is concerned, be treated as adequate if -

(as for other substances)

(a) that occupational exposure standard is not exceeded, or

(b) where that occupational exposure standard is exceeded, the employer identifies the reasons for the standard being exceeded and takes appropriate action to remedy the situation as soon as is reasonably practicable.

(6) Subject to regulation 17(2) (which relates to transitional provisions), where respiratory protective equipment is provided in pursuance of this regulation, then it shall -

(as for other substances)

(a) be suitable for the purpose; and

(b) be of a type approved or shall conform to a standard approved, in either case, by the Health and Safety Executive.

(7) In this regulation, "adequate" means adequate having regard only to the nature of the substance and the nature and degree of exposure to substances hazardous to health and "adequately" shall be construed accordingly.

(as for other substances)

(8) In the event of the failure of a control measure which might result in the escape of carcinogens into the workplace, the employer shall ensure that -

(a) only those persons who are responsible for the carrying out of repairs and other necessary work are permitted in the affected area and they are provided with appropriate respiratory protective equipment and protective clothing; and

(b) employees and other persons who may be affected are informed of the failure forthwith.

Draft amendments to General Approved Code of Practice

(Changes are shown in **bold type**)

Substances Hazardous to Health

1 The COSHH Regulations apply to substances that have already been classified as being very toxic, toxic, harmful, corrosive or irritant under the Classification, Packaging and Labelling of Dangerous Substances Regulations 1984 and to those substances which have maximum exposure limits or occupational exposure standards. COSHH also covers substances that have chronic or delayed effects, for example, substances that are carcinogenic, mutagenic or teratogenic. A substance should be regarded as hazardous to health if it is hazardous in the form in which it occurs in the work activity, whether or not its mode of causing injury to health is known, and whether or not the active constituent has been identified. A substance hazardous to health is not just a single chemical compound but also includes mixtures of compounds, micro-organisms, allergens, etc.

2 COSHH includes special provisions for carcinogens in Regulation 7 as modified by Schedule 10. For guidance on risks from carcinogens, employers should read this Code together with the supporting Carcinogens Approved Code of Practice. Medical research on occupational cancer continues to find further substances and processes to which varying degrees of suspicion of causing cancer are attached. It is therefore important to have an active precautionary policy of prevention and control based on up to date knowledge of the growing list of substances which are suspected of being carcinogenic but are not yet subject to Schedule 10 and the Carcinogens ACOP. The need for prudence applies particularly to substances which have not previously been considered to be hazardous in this way, or perhaps in any way, since they are more likely to have been used without particular care. Prevention is better than cure with all diseases; with occupational cancer and other diseases where the effects of exposure are often irreversible, prevention may be the only cure.

3 to 13 [previously 2 to 12] - unchanged.

14 [was 13] A suitable and sufficient assessment should include:

- (a) an assessment of the risks to health;
- (b) **consideration of the practicality of preventing exposure to hazardous substances;**
- (c) [was (b)] the steps which need to be taken to achieve adequate control of exposure **where prevention is not reasonably practicable**, in accordance with regulation 7; and
- (d) [was (c)] identification of other action necessary to comply with regulations 8-12.

15 to 22 [previously 14 to 21] - unchanged

Review of assessment

23 [was 22] The assessment should be reviewed **regularly and in any case** whenever there is any evidence to suspect that it is no longer valid or where there has been a significant change in the work to which the assessment relates.

24 and 25 [previously 23 and 24] - unchanged.

26 **Arrangements should be made to ensure that the assessment is reviewed regularly. The assessment should include a decision, and where the assessment is written, a statement, specifying the maximum period which should elapse between the date of the initial assessment and the date of the first review, and then between successive reviews. The length of the period chosen will depend on the nature of the risk, the work and a judgment on the likelihood of changes occurring, but should usually be between two and five years.**

27 **Reviews triggered by these arrangements will provide the opportunity to reconsider the practicability of preventing exposure to hazardous substances**

by changes to the process or by the use of less hazardous substances. This might now be practicable because of technological changes, or because of changes in the relationships between costs of substances, equipment used and control measures, since the last assessment. Similarly, control measures should be re-examined to assess the feasibility of further improvement; for example, where substances with MELs are involved, do the controls really reduce exposure as far as is reasonably practicable, or merely below the MELs?

PREVENTION OR CONTROL OF EXPOSURE TO SUBSTANCES HAZARDOUS TO HEALTH

28 [was 25] Regulation 7(1) sets out the general duty: the employer must ensure that the exposure of employees to substances hazardous to health by any route (eg inhalation, ingestion, absorption through the skin or contact with the skin) is either prevented or, where this is not reasonably practicable, adequately controlled.

29 [was 26] Adequate control will have been achieved if the standards set out in paragraphs 36 to 39 have been met.

Prevention of exposure

30 [was 34(a)] For all hazardous substances in the workplace, the employer must give first priority to trying to prevent exposure. This might be achieved by:

- (a) changing the method of work so that the operation giving rise to the exposure is no longer necessary;
- (b) modifying the process to eliminate production of a hazardous by-product or waste product; or
- (c) where a hazardous substance is used intentionally, substitution by a new substance or different form of the same substance which, in the circumstances of the work, presents no risk or less risk to health.

31 It is important when considering substituting one substance for another to take into account all the potentially harmful properties of any proposed

replacement and to balance any new risks they might present against the possible benefits. For example, in seeking a less toxic substitute chemical for a process, the choice of one with lower toxicity but higher flammability might increase the overall risk if the process has an intrinsic fire risk.

Prevention or control of exposure to carcinogens

32 Regulation 7(1A) introduces the special provisions contained in Schedule 10 to the Regulations for prevention or control of exposure to carcinogens. These provisions state that, for carcinogens, if complete prevention is not reasonably practicable, the control measures listed in the Schedule as regulation 7(2)(a)-(h) must all be taken. This means that whether or not it is reasonably practicable to totally enclose the process and handling systems in accordance with regulation 7(2)(a), all the other measures in 7(2)(b)-(h) are still required. Regulation 7(8) deals with failures of control which might result in the escape of carcinogens into the workplace, limiting access to the affected area to those carrying out repairs and other necessary work. This would include any essential attendance by the emergency services.

Control of exposure to substances not classified as carcinogens

33 [was 32 & 34(b)] For substances not classified as carcinogens, where prevention of exposure is not reasonably practicable, adequate control of exposure should be achieved by measures other than personal protective equipment, so far as is reasonably practicable, in the light of the degree of exposure, circumstances of use of the substance, informed knowledge about its hazards and current technical developments. Other control measures could be any combination of the following:

- (a) [was (i)] totally enclosed process and handling systems;
- (b) [was (ii)] plant or processes or systems of work which minimise generation of, or suppress or contain, the hazardous dust, fume, micro-organisms etc and which limit the area of contamination in the event of spills and leaks;

- (c) [was (iii)] partial enclosure, with local exhaust ventilation;
- (d) [was (iv)] local exhaust ventilation;
- (e) [was (v)] sufficient general ventilation;
- (f) [was (vi)] reduction of numbers of employees exposed and exclusion of non-essential access;
- (g) [was (vii)] reduction of the period of exposure for employees;
- (h) [was (viii)] regular cleaning of contamination from, or disinfection of, walls, surfaces etc;
- (j) [was (ix)] provision of means for safe storage and disposal of substances hazardous to health;
- (k) [was (xi)] prohibition of eating, drinking, smoking, etc in contaminated areas;
- (l) [was (xii)] provision of adequate facilities for washing, changing and storage of clothing, including arrangements for laundering contaminated clothing.

Review of control measures

34 [was 35] - unchanged

Emergencies

35 [was 36] - unchanged

Adequate control - exposure by inhalation

Substances assigned a maximum exposure limit (MEL)

36 [was 27] - unchanged

Substances assigned an occupational exposure standard (OES)

37 [was 28] - unchanged

Other inhaled substances

38 [was 29] - unchanged

Adequate control - Exposure by routes other than inhalation

39 [was 30] - unchanged

Measuring levels of exposure

40 [was 31] - unchanged

Situations where personal protective equipment may be necessary

41 [was 33] - unchanged

Standards for personal protective equipment

42-45 [previously 37-40] - unchanged

Facilities for washing, clothing accommodation, eating, drinking

46 [was 41] Adequate washing facilities should be provided in order to enable persons exposed to meet a standard of personal hygiene consistent with the adequate control of exposure and the need to avoid the spread of substances hazardous to health. The washing facilities should be conveniently accessible but situated so that they do not themselves become contaminated; the type of facilities provided should be related to the nature and degree of exposure.

Employers should be aware that they may also have duties under the Workplace (Health, Safety and Welfare) Regulations 199- in relation to the provision of washing facilities.

47 [was 42] Clothing accommodation should be provided when personal protective clothing is used or when there is a risk of contamination of outdoor clothing by substances hazardous to health. The changing facilities should be located and designed so as to prevent the spread of contamination from protective clothing to personal clothing and from one facility to another. **Employers should be aware that they may also have duties under the Workplace (Health, Safety and Welfare) Regulations 199- in relation to the provision of changing facilities.**

48 [was 43] - unchanged

49 [was 44] Wherever it is necessary to prohibit eating or drinking, suitable facilities should be set aside for these activities to be carried out in an uncontaminated area. **This is also a requirement of the Workplace (Health, Safety and Welfare) Regulations 199- in workplaces where those Regulations apply.** The facilities should be conveniently accessible to the working area and to washing facilities and users should wash before eating or drinking etc in order to reduce the risk of ingestion.

50-91 [previously 45-86] - unchanged

92 [was 87] The collection, maintenance and review of health records (see Appendix, para 1(a)) may protect the health of workers through the detection and evaluation of risks to health. In some cases, the only health surveillance required is the collection and maintenance of those records - examples are:

- (a) known or suspected carcinogens (eg **substances defined as carcinogens in regulation 2(1)**) other than those already included in Schedule 5 to the Regulations or in paragraph 91 [was 86] above;

(b) to (d) - unchanged

Remainder unchanged apart from paragraph references to the Appendix - Health
Records: (Code paragraphs **93,97** and **98**) [previously 87,91 and 92]

Carcinogens ACOP Revised Draft

(Changes are shown in **bold type**)

Scope of this Code

1 This Code applies where persons are exposed, or are liable to be exposed, to substances **which are defined as carcinogens in the Control of Substances Hazardous to Health Regulations 1988 as amended by the Control of Substances Hazardous to Health (Amendment) Regulations 1992.**

2 While the application of this Code depends on the potential of a substance to cause cancer, whether it does so in practice will depend on the nature and degree of exposure to it. The precautions which are required to be taken under the Regulations will be determined by the extent of the risk of cancers occurring and the scope for minimising that risk.

3 This Carcinogens Code is intended **to give practical guidance on Schedule 10 to the Regulations** and certain aspects of the General Approved Code of Practice; it is in no way a replacement for **the latter**. Both Codes are concerned with the correct matching of the precautions to the risk and should therefore be treated as complementary.

Prohibitions relating to certain substances (Regulation 4)

4 The prohibited substances are listed in full in Schedule 2 to the Regulations. The following prohibitions relate to **carcinogens**:

- (a) employment in the manufacture and use, including any process resulting in the formation, of 2-naphthylamine, benzidine, 4-aminodiphenyl, 4-nitrodiphenyl and their salts and any substance containing any of these compounds in a total concentration equal to or greater than 0.1%;
- (b) importation of the 4 substances above;
- (c) use for all purposes except use in industrial processes, and for the purposes of research, development and analysis, of benzene and any other

substance containing benzene in a concentration equal to or greater than 0.1%, other than motor fuels covered by EC Directive 85/210/EEC and waste covered by EC Directives 74/442/EEC and 78/319/EEC.

5 Exemption Certificates may be granted by the Health and Safety Executive under certain conditions laid down in Regulation 14. Holders of Certificates of Exemption and Import Licences issued by the Health and Safety Executive under the Carcinogenic Substances Regulations 1967 and the Carcinogenic Substances (Prohibition of Importation) Order 1967 (now repealed) should **have already re-applied** to the Executive under Regulation 14 of the Control of Substances Hazardous to Health Regulations if they **wished** to seek exemption from the requirements of Regulation 4.

Assessment of health risks created by work involving substances hazardous to health (Regulation 6)

6 The General Code gives guidance on assessment. Assessment has an especially vital role to play in the control of carcinogenic substances. Because the development of the clinical effects of cancer may take place many years after first exposure there may not be any early warnings of adverse effects. The assessment should identify whether substances to which this code relates are present and, if so, the nature and extent of the risk; it should ensure that the information obtained is used to plan effective control measures and other precautions. **(The Appendix gives some relevant background information.)**

7 For any substance to which this Code applies, the results of assessment should at least include details of:

- (a) the nature of the hazard and the nature and extent of exposure, **including the identification of any workers who may be at particular risk;**
- (b) whether substitution by less hazardous substances is reasonably practicable;
- (c) the control measures to be applied to prevent or control exposure and **evidence that consideration has been given to not employing workers at particular risk in areas where they may be exposed to carcinogenic substances, such as pregnant women dealing with a transplacental carcinogen;**

- (d) operating and maintenance instructions and procedures, where relevant to ensure that exposure is minimised;
- (e) precautions under non-routine conditions, **including maintenance activities and emergencies;**
- (f) use of personal protective equipment;
- (g) monitoring procedures;
- (h) health surveillance procedures;
- (j) arrangements for consultation with employers and their representatives, including procedures for reporting defects in plant or precautions, and details of essential information and training requirements.

8 [was un-numbered] Because it is particularly important to ensure accuracy and continuity of knowledge and action over time, the assessment and the results of the assessment should normally be recorded where carcinogens are involved. **The assessment should be reviewed:**

- (a) **whenever there is any indication, from monitoring results or other sources of information, that standards of control have changed significantly; and**
- (b) **within the period set in the assessment for regular automatic review, as described in the General ACOP, paragraph 26.**

Prevention or control of exposure to carcinogenic substances (Regulation 7, Schedule 10)

9 [was 8] Prevention of exposure to the carcinogenic substance must be the first objective, in view of the serious and often irreversible nature of the disease. Carcinogenic substances or processes should not be used or carried on where there is an equivalent but less **or non-hazardous** substitute. Carcinogenic, toxic and other properties of possible **chemical** substitutes should be established and taken into account when considering changes. Synthetic routes for the production of chemicals should be chosen in order:

(a) to avoid the use of carcinogenic starting materials; and

(b) (together with the conditions under which substances are used) to avoid, if possible, the formation of by-products, intermediates, wastes or residual contaminants consisting of or containing carcinogenic substances.

Control of exposure (Regulation 7 and Schedule 10)

10 [was 9] If the use of a safer alternative substance or process is not reasonably practicable, adequate control of exposure must be ensured. The General Approved Code of Practice gives guidance on the meaning of "adequate control"; in the case of carcinogens, it is particularly important that exposure should be controlled to as low a level as is reasonably practicable, bearing in mind the high risk of death associated still with many forms of cancer and the fact that the level of exposure affects only the probability of cancers occurring in any exposed population, not the severity of the disease in individuals.

11 [was part of 9] The use of totally enclosed systems must be the first choice of control measure for carcinogens. Where this cannot be achieved plant or processes or systems of work should be so designed and operated that they minimise the generation of, or suppress and contain carcinogenic substances, for example through the partial enclosure of processes and handling systems, appropriate local exhaust ventilation systems, and general ventilation. Control measures inside the workplace must not be applied in ways which produce risks in other workplaces. Any environmental legislative requirements must also be taken into account;

12 [was 10] Carcinogenic substances intended for use should be kept to the minimum needed for the process, and, where appropriate, stored and transported on site in closed containers, clearly labelled and with clearly visible warning and hazard signs. There may, however, be circumstances where, to ensure the adequate control of exposure, it is preferable to store a large quantity in a controlled manner than to deal with frequent supplies of smaller volume. Carcinogenic waste products should be clearly labelled and stored securely until such time as they are removed by a competent specialist contractor, or are disposed of safely on site by incineration or in a way that does not accentuate the risk to other workers or the outside environment.

13 [was 10/11] The areas in which exposure to carcinogens may occur should be clearly **identified** and measures taken to prevent the spread of contamination **within and** beyond these areas. The number of people liable to be exposed to a carcinogenic substance and the duration of their exposure should be kept to the minimum necessary for the work. Non-essential personnel should [generally] be excluded.

14 [was 12 & General ACOP] **Eating, drinking and smoking should not be permitted where there is a risk of contamination from the carcinogenic substance.** **Appropriate warning signs should be used.** Areas should be set aside where people can eat, drink, and smoke without risking contamination by the substance. Appropriate hygiene measures should include the establishment of a cleaning regime to remove contamination from walls, surfaces etc. Adequate washing facilities should be provided in order to enable persons exposed to meet a standard of personal hygiene consistent with adequate control of exposure and the need to avoid the spread of carcinogenic substances.

15 If in spite of the above control measures there is an uncontrolled release of a carcinogenic substance into the place of work, means, including emergency procedures, shall be available for limiting the extent of risks to health and for regaining adequate control as soon as possible. Only those persons who are essential to the carrying out of repairs and other necessary work should be permitted to work in the affected area.

16 [was 13] In all cases prevention or adequate control of exposure should be achieved by measures other than personal protective equipment, so far as is reasonably practicable in the light of the degree of exposure, circumstances of use, informed knowledge about its hazards and current technical developments. If the use of personal protective equipment and clothing is unavoidable eg during a plant failure or maintenance operations, the advice in the General Approved Code of Practice on its application, use and maintenance should be followed.

Monitoring exposure at the workplace (Regulation 10)

17 [was 14] Because exposure to carcinogens can result in a serious health effect, monitoring is normally requisite, as indicated in paragraph 73 [was 68] of the General Code. A monitoring programme should be established and used where necessary in order to determine the extent of exposure of individuals in

comparison with prescribed or approved occupational exposure limits or, if none exist, self-imposed working standards, to detect any deterioration in standards of control.

Health Surveillance (Regulation 11)

18 [was 15] The General Approved Code of Practice gives guidance on health surveillance. In the case of carcinogenic substances, some of the objectives of health surveillance and its limitations need to be emphasised.

19 [was 16] Health surveillance is appropriate in the cases of all carcinogenic substances, unless exposure is not significant (see paragraph 93 [was 88] of the General Code). Some are listed in Schedule 5 to the Regulations, as requiring medical surveillance under the supervision of an employment medical adviser or appointed doctor. In the cases of substances known to, or suspected of, causing cancer of the skin (eg arsenic, coal soots, coal tar, non-solvent refined mineral oils, contaminated used mineral oils), health surveillance should include regular skin inspection by a suitably qualified person, or, alternatively, regular enquiries by a responsible person about any symptoms, following self-inspection by the employees concerned. In all other cases, only a health record, as described in paragraph 92 [was 87] and paragraph 2 of the Appendix to the General Code, need to be kept.

20 [was 17] Health surveillance generally has limitations in identifying susceptible persons and in the early recognition of cancer at a stage when treatment is likely to offer a better prognosis. For this reason it is largely restricted to the keeping of health records under these Regulations, in order to protect the health of workers through the detection and evaluation of risks to health. Medical surveillance by an employment medical adviser or appointed doctor is, however, required in those cases included in Schedule 5, and, in addition, skin cancer is an obvious example where appropriate health surveillance can detect the condition at an early stage when it can be cured.

21 [was 18] In view of the usual latent period between exposure to a carcinogenic substance and any health effect, employees who have been exposed to carcinogenic substances should be provided with information about any need for continuing health surveillance after exposure has ceased.

Information, instruction and training for persons who may be exposed to substances hazardous to health (Regulation 12)

22 [was 19] The General Code gives guidance on the provision of information, instruction and training. Because the risk of cancer from exposure to a substance cannot in most cases be presumed to be reduced to zero except by eliminating exposure and because there may be no short-term manifestation of adverse effects, it is especially important to ensure that the information, instruction and training provided is of an appropriately high standard to ensure that employees are aware of risks, **including the additional risks due to tobacco consumption**, and the need for control of exposure to be maintained. **Where there is an uncontrolled release of a carcinogenic substance into the workplace, unless exposure is not significant, workers who may be affected must be informed of the situation as soon as possible and should have received sufficient instruction and training to ensure that emergency procedures are effective.**

23 [was 20] Persons exposed, or liable to be exposed, to carcinogenic substances, and their representatives at the workplace, should be made aware of the nature of the risk, the special features of carcinogenic substances and the circumstances in which they may be exposed to carcinogenic substances, in addition to the information specified by the General Code.

[Appendix 1 no longer needed - incorporated in Schedule 10 to the Regs]

Appendix - Background - occupational cancer - [was Appendix 2] - unchanged

EXPLANATORY NOTES

DRAFT AMENDMENTS TO COSHH REGULATIONS - SCHEDULE 1

BIS(CHLOROMETHYL) ETHER (BCME)**Current Control Measures**

1 BCME has not previously been assigned a MEL or an OES under COSHH. It is currently listed in Table 4 of Guidance Booklet EH40/91 with the advice that, until it is reviewed by ACTS/WATCH, exposure should be controlled in accordance with paragraph 29 of the COSHH General ACOP and that a limit of 0.001 ppm 8-hour TWA should be used as guidance for the control of exposure under Regulation 7(1) of COSHH.

Proposed Change

2 Following a review by ACTS it is proposed that BCME should be assigned a MEL of 0.001 ppm 8-hour TWA (0.005 mg m⁻³ 8-hour TWA).

Summary of Health Effects

3 The health effects following exposure to BCME have been reviewed by HSE's Toxicology Unit, in Toxicology Review No 22: Review of Bis(Chloromethyl) Ether. (HMSO, ISBN 0-11-885524-7).

4 BCME is a potent lung carcinogen. The cancer is highly characteristic, tending to occur in young workers, relatively soon after exposure to BCME. The evidence linking lung cancer to BCME exposure is derived from occupational sources, although reliable exposure levels have not been recorded in cases where cancer has occurred.

5 The Commission accepted that in the light of current knowledge it is not possible to identify a threshold for the carcinogenicity of BCME. The

Commission therefore concluded that it would be appropriate to assign a MEL to BCME.

Industrial implications

6 In the UK, BCME has not been manufactured or supplied as a commercially available chemical, except in laboratory quantities, since the mid 1970s.

7 At present BCME is known to be deliberately generated, or to occur as an impurity or by-product, at four sites in the UK during the synthesis of organic compounds in specialised sections of the chemical manufacturing industry.

8 The introduction of a MEL of 0.001 ppm 8-hour TWA will not have serious consequences for industry, although in one case further work on additional control measures may be required in order to reach this standard.

9 Methods for monitoring personal exposure are available, but some investment may be required in order to implement these techniques at all locations.

BENZENE

10 It is not proposed to amend the existing MEL of 5 ppm 8-hour TWA. However, it is proposed to make a slight change to the derived equivalent value in mg m^{-3} as a result of using a more accurate conversion process.

Existing MEL values (EH40/91)

5 ppm/15 mg m^{-3} 8-hour TWA

Proposed MEL values

5 ppm/16 mg m^{-3} 8-hour TWA